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10/806,038

03/22/2004

Sally Mackenzie

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02/28/2008

JONDLE & ASSOCIATES P.C.

858 HAPPY CANYON ROAD SUITE 230

CASTLE ROCK, CO 80108

EXAMINER

KUBELIK, ANNE R

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/806,038 | Applicant(s) MACKENZIE ET AL. | |
| | Examiner Anne R. Kubelik | Art Unit 1638 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claim 15 is pending.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The rejection of claim 15 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Fauron et al (2002, US Patent 6,346,612) is withdrawn in light of Applicant's amendment of the claim.

Claim Rejections - 35 USC § 112

4. Claim 15 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 30 August 2007. Applicant's arguments filed 29 November 2007 have been fully considered but they are not persuasive.

The claim is broadly drawn to any cytoplasmic male sterile plant made by suppressing the expression of an MSH1-homologous gene in the plant.

The instant specification, however, only provides guidance for identification of the MSH1 gene from Arabidopsis by gene mapping and cloning (example 1), comparison to potential CHM genes from other plant species (examples 2 and 3 and Figs 2-3); and transformation of Arabidopsis with the first 213 of the AtMSH1 gene (example 3). The only other guidance for reducing the expression of MSH1 in a plant is general (¶107-112). No

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cytoplasmic male sterile plant was made by suppressing the expression of an MSH1-homologous gene in a plant.

The instant specification fails to provide guidance for how to make a cytoplasmic male sterile plant made by suppressing the expression of an MSH1-homologous gene in the plant.

The specification in ¶13-14, 34, 107-109 discusses three ways in which MSH-1 expression may be suppressed - 1) by RNAi, antisense, ribozymes or cosuppression (¶107-111), and 2) by a compound, which includes a protein or an antibody (¶13-14, 34, 116-121).

The specification fails to teach RNAi, antisense, ribozyme and cosuppression constructs that can be used to suppress the expression of an MSH1-homologous gene in maize, wheat, rice, sorghum, tomato, potato, soybean and/or millet.

The specification fails to teach how to use a protein or other compound to suppress the expression of an MSH1-homologous gene in a plant.

Sandhu et al (2007, Proc. Natl. Acad. Sci. USA 104:1766-1770) and the Declaration of Sally Mackenzie, filed 21 February 2007, state that mutation of the MSH1 gene in Arabidopsis does not create cytoplasmic male sterile plants (Sandhu et al, pg 1766, right column, paragraph 3; Declaration, pg 1). Thus, the only exemplified transformation would not produce the claimed cytoplasmic male sterile plants.

Further, Sandhu et al teach that suppression of Msh1 in tobacco and tomato required at least one crossing step (Table 1), which is not taught by the instant specification, and not present in the instant claims.

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate a

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cytoplasmic male sterile plant made by suppressing the expression of an MSH1-homologous gene in the plant.

Applicant urges that paragraph 17 teaches that antisense constructs can be used to suppress MHS-1 and paragraph teaches RNAi; thus, the specification teaches constructs that can be used in the claimed invention (response pg 3).

This is not found persuasive because the specification fails to teach any antisense or RNAi constructs to use in the method.

Applicant urges that Fig 3 identifies soybean, rice, tomato and common bean MSH1 amino acid consensus sequences (response pg 3-4).

This is not found persuasive because protein consensus sequences are not the same thing as DNAs or RNAs or other compounds that suppress the expression of an MSH1-homologous gene. Further, no potato sequence is indicated.

Applicant urges that the statement “waits two generations of selfing” does not indicate that two generations are required, but that they were done; the crossing information in Sandhu was not necessary and only done to confirm that male sterility was cytoplasmic (response pg 4).

This is not found persuasive because in the response filed 14 June 2007 Applicant said: “[T]he investigator introduces an RNAi construction by transformation, regenerates the plants, and waits two generations of selfing until male sterility emerges” (emphasis added). As selfing is a form of crossing, a crossing step is clearly required. The phrase “waits two generations of selfing”, as it is used in that statement, indicates that the selfing is required.

Applicant urges that suppression is well-known in the art; thus, undue experimentation is not required (response pg 4).

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This is not found persuasive because selfing/crossing steps are required, and because the specification fails to teach any construct that can be used to produce the claimed plant.

5. Claim 15 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 30 August 2007. Applicant's arguments filed 29 November 2007 have been fully considered but they are not persuasive.

The claim is broadly drawn to any cytoplasmic male sterile plant made by suppressing the expression of an MSH1-homologous gene in the plant.

The specification fails to describe the structure of the DNA, RNA, protein or other compound required for the recited function of suppressing the expression of an MSH1-homologous gene in maize, wheat, rice, sorghum, tomato, potato, soybean and/or millet.

No DNA, RNA, protein or other compound species that suppress the expression of an MSH1-homologous gene are described or reduced to practice in the specification.

Because the DNA, RNA, protein and other compounds that suppress the expression of an MSH1-homologous gene are not described, the method of using the DNA, RNA, protein and other compounds to suppress the expression of an MSH1-homologous gene is likewise not described, and the specification fails to provide an adequate written description of the claimed invention.

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Further, the specification fails to describe the structural features of plant mutants what are cytoplasmically male sterile because an MSH1-homoglous gene has been suppressed in one of its parents. How does one distinguish a plant that is cytoplasmically male sterile because an MSH1-homoglous gene has been suppressed in one of its parents from a plant that is cytoplasmically male sterile for other reasons?

Therefore, given the lack of written description in the specification with regard to the structural and functional characteristics of the claimed compositions, it is not clear that Applicant was in possession of the claimed genus at the time this application was filed at the time this application was filed.

Applicant urges that the claims have been amended to limit the plants to soybean, tomato, rice and common bean, for which MSH1 amino acid consensus sequence are presented (response pg 4).

This is not found persuasive because protein consensus sequences are not the same thing as DNA, RNA, protein or other compounds that suppress the expression of an MSH1-homologous gene. Further, the specification fails to describe the structural features of plant mutants what are cytoplasmically male sterile because an MSH1-homoglous gene has been suppressed in one of its parents. How does one distinguish a plant that is cytoplasmically male sterile because an MSH1-homoglous gene has been suppressed in one of its parents from a plant that is cytoplasmically male sterile for other reasons? What is the structural difference in the mitochondrial genome?

Claim Rejections - 35 USC §§ 102 -103

6. Claim 15 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sun et al (2001, US Patent 6,320,098).

Sun et al teach a cytoplasmically male sterile soybean plants (claim 1). The prior art plants differ from the claimed plants only by their method of manufacture. However, the claimed method of making the cytoplasmically male sterile plants would not distinguish them over the cytoplasmically male sterile plants taught by the prior art. See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the

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USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Anne Kubelik, Ph.D.
March 1, 2008

/Anne R. Kubelik/
Primary Examiner, Art Unit 1638